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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,862

12/15/2005

Leifeng Cheng

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ROPES & GRAY LLP

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EXAMINER

TUCKER, ZACHARY C

ART UNIT

PAPER NUMBER

1624

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,862	Applicant(s) CHENG, LEIFENG	
	Examiner Zachary C. Tucker	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8 and 10-14 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3,6 and 12-14 is/are allowed.
- 6) ☒ Claim(s) 4,5,8,10 and 11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>15Dec05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of obesity, bulimia, and extended abuse, addiction and/or relapse disorders, does not reasonably provide enablement for the other indications recited in the claim. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

When making the determination of scope of enablement of a claim, the Office customarily relies on the factors promulgated in the decision rendered for *In re Wands*, 858 F.2d 731, 737 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), which are:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Each of these factors will be addressed, with respect to the method claimed in instant claim 10.

- (A) The claim is quite broad; treatment of a wide variety of disorders is specified.

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Treatment of neurological disorders (in general) is specified. Treatment of memory, psychiatric, cognitive, immune, cardiovascular, reproductive and endocrine disorders (in general) is specified as well. Treating epilepsy and “related conditions” is specified also. Treatment of “diseases related to the respiratory and gastrointestinal system” is specified furthermore. Treatment of several specific diseases is also specified in the claim (schizophrenia, bipolar disorders, anxiety, anxio-depressive disorders, depression, anorexia, Parkinson's disease, Huntington's chorea, Alzheimer's disease).

(B) The nature of the invention is that of a medical treatment method.

(C) The state of the prior art is well-exemplified by the following article, authored by Di Marzo:

Vincenzo Di Marzo et al, “Leptin-regulated endocannabinoids are involved in maintaining food intake” *Nature*, vol. 410, pages 822-825 (12 April 2001).

The Di Marzo article teaches that at about the time the present invention was made, in 2001, cannabinoid CB1 receptor *antagonists* were known to be plausible as treatment for overeating and/or obesity. Compounds of the present invention are antagonists or inverse agonists at the CB1 receptor. Other utilities for antagonists of the CB1 receptor were hypothesized at the time the invention was made, but the only substantial utility for which evidence had been shown was reduction food intake. As evidence that reduction of food intake/treatment of obesity/treatment of overeating was a plausible utility for CB1 receptor antagonists at the time the invention was made, the examiner would cite the Di Marzo article.

Agonists of CB1 receptor, on the other hand, were known to increase memory, decrease pain, and increase appetite among other things, at the time the invention was

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made. It appears that instant claim 10 embraces treatment of many disorders/diseases which are treatable with cannabinoid *agonists*, but not antagonists.

(D) The level of ordinary skill in the relevant art is that of a physician experienced in treating the recited diseases in the claim.

(E) Medical treatment methods are by no means predictable, although it can be predicted in the instant case that the full scope of instant claim 10 is not practicable with the compound according to instant claim 1, or a formulation according to instant claim 8 (see above, point “(C)”).

(F) The instant specification provides guidance relating to well-understood pharmaceutical dosage forms, and alleges that the compounds of the invention are useful in the manner prescribed by instant claim 10 (pages 25-31).

(G) There are no working examples of the treatment of any condition recited in instant claim 10, by administering an effective amount of a compound of claim 1 or a formulation according to claim 8.

(H) In light of the above findings, it is presumed that in order to practice the full scope of instant claim 10, there would have to be an undue amount of experimentation conducted by whosoever would do so.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, 8 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 4, from which claim 5, and claims 8 and 11 (in part) depend, the definition of R_j includes the term "azolactonyl." This is not descriptive of any particular heterocyclic group. At best, it could be said that the term means a lactone which contains a nitrogen atom, but "lactonyl" is not descriptive of any particular heterocyclic group either.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term 'epilepsy, and related conditions' is not seen as being clear and well-defined, within the meaning of 35 U.S.C. 112.

Suppose a person had epilepsy, and also a headache. Is the headache a "related condition?"

Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday to Friday from 9:00am to 5:00pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

/Zachary C. Tucker/
Primary Examiner, Art Unit 1624